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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,690	LEGRAND ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,10,13-22 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,13-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 1/12/2010 is acknowledged and has been entered. Claims 1 and 3-6 have been amended. Claims 1-6, 9, 10, 13-22 and 24 are pending and are examined herein on the merits for patentability.

Response to Arguments

Any rejection not reiterated herein has been withdrawn as being overcome by amendment.

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Declaration under 37 CFR 1.132

The declarations under 37 CFR 1.132 filed 1/12/2010 is sufficient to overcome the rejection based upon 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims are drawn to the pharmaceutical dosage form according to claim 7. However, claim 7 is a cancelled claim. As such, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, 10, 13-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthwaite et al. (US Pre-Grant Publication 2002/0132001).

Garthwaite et al. teach a composition comprising dual antihypertensive agents wherein the first of said agents is taught as eplerenone and the second of which is taught as preferably being a different antihypertensive agent such as a diuretic or an ACE inhibitor (claims 1, 9, 10 and 14), including those set forth in paragraph 0087-9.

The composition is further taught as a capsule comprising enterically coated pellets (claim 17). Said pellets are taught as having a preferred core formulation comprising cellulose or cellulose derived material [0132] and more preferably lactose or microcrystalline cellulose [0133]. The uncoated cores are taught as being in the form of generally spherical beads having a diameter of 1,000 microns or less and preferably ranging from about 200-800 microns [0141]. In the case of the coated, active-loaded core, typical diameters, particularly in the case of pellets or beads, ranges from 200 to 1700 microns [0140]. Enteric coatings on the cores are taught as being used to control the release of the antihypertensive formulations contained therein [0146]. The coating is taught as being produced from copolymers of acrylic acid and methacrylic acid or esters of either monomer, which are referred to overall as "polymerized acrylates" [0147]. Specific examples of polymerized acrylates include Eudragit® L and Eudragit® S, the commercial brand names for methacrylic acid/methyl methacrylate copolymer (see *Degussa Specifications and Test Methods*). In addition to the polymers, the coating layer typically includes a lubricant such as hydrogenated vegetable oils [0155], [0124] and [0125] (e.g. sterotex, which is hydrogenated cottonseed oil). The polymeric coating is taught as comprising about 10-50% by weight of polymerized acrylates [0148] and the lubricants, if present, are taught as ranging between 0.1-10% by weight [0126]. Mixed together in the enteric coating, a ratio of polymerized acrylates to lubricant is established, such as 10%:10% or 1:1. Additional excipients are taught such as diluents, disintegrants, binding agents and wetting agents are taught [0106] – [0123]. Dosage formulations such as tablets and hard gelatin capsules are taught by Examples 1-3 and

4-7, respectively. Claims 19-21 teach orally administering the composition discussed above as a means for treating humans for elevated blood pressure.

Garthwaite does not specifically recite dissolution behavior at pH 1.4 and 6.8.

It would have been obvious to one of ordinary skill in the art at the time of the invention to select hydrogenated cottonseed oil as a lubricant for use in enterically coated microparticles. The Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham. One such rationale includes choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See MPEP 2143. In the instant case, the lubricant components disclosed by Garthwaite and their functions were known in the art at the time of the instant invention. For example, Garthwaite teaches that lubricants control the rate of hydration and permeability of the enteric coating diffusion barrier. One of ordinary skill in the art could have selected one known lubricant from the discrete list of suitable lubricants disclosed by Garthwaite and the results would have been predictable, that is formulation of an enteric coating having a lubricant incorporated therein for controlling the rate of hydration and permeability of the enteric coating diffusion barrier.

With respect to the claimed dissolution properties at pH 1.4 and 6.8, the Office does not have the facilities for examining and comparing applicant's product with the

product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. The claims are descriptive and thus would be an inherent property of the claimed composition. In the absence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Since Garthwaite teaches the same particle size, same enteric polymer, same lubricant, same ratio of polymer:lubricant, and same mass fraction of enteric coating, it is interpreted absent evidence to the contrary that the formulation would be capable of achieving the same dissolution profile, especially since both the Garthwaite document and the instant claims are drawn to delayed release formulations. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure or composition as that which is claimed, the properties applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is (571)272-

9928. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday 9 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS